92-1576

No. _____

Supreme Court, U.S.
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In The

Supreme Court of the United States

October Term, 1992

ROBERT M. SINSKEY,

Petitioner,

v.

PHARMACIA OPHTHALMICS, INC.,

Respondent.

Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

PETITION FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Under Fed. R. Civ. P. 56(c), which requires that for the granting of summary judgment that there be "no genuine issues of material fact," is it proper to grant summary judgment where a patent inventor's experimental activities are evidenced by declaration and deposition testimony, and can such declaration and deposition evidence be ignored by the Court of Appeals for the Federal Circuit?

2. In a summary judgment proceeding, can a district court or court of appeals resolve allegations of conflicting testimony, and whether there is an actual conflict in testimony, or is such a determination a violation of *Anderson v. Liberty Lobby*, which requires that all factual issues must be resolved in favor of the non-moving party; and should the Supreme Court resolve a conflict between the 5th Circuit and the Court of Appeals for the Federal Circuit on this issue?

3. In a patent infringement action, where there is an issue as to whether a physician's testing of the patented device was experimental use or public use, what are the standards of experimental use, and do they adequately protect the public from products which have not been fully tested?

Pursuant to Rule 29.1, petitioner states that he is an individual and has no parent companies or subsidiaries.

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Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

PETITION FOR WRIT OF CERTIORARI

Petitioner, Robert M. Sinskey, respectfully prays that a writ of certiorari be issued to review the judgment of the United States Court of Appeals for the Federal Circuit entered on December 28, 1992.

OPINIONS BELOW

The opinion of the court of appeals (A1) of which review is sought is reported at 982 F.2d 494, 25 U.S.P.Q. 2d 1290 (Fed. Cir. 1992). The opinion of the district court (A13) is not reported.

JURISDICTION

The judgment of the court of appeals (A30) was entered on December 28, 1992. A petition for rehearing was rejected on January 27, 1993. (A33) This writ is being filed within 90 days of the entry of judgment of the court of appeals.

This Court has jurisdiction to review the judgment of the court of appeals under 28 U.S.C. § 1254 (1).

STATUTORY PROVISIONS INVOLVED

This case involves the following statutory rules and provisions, which are set out in full in the appendix at A35:

35 U.S.C. § 102 (b)

Fed. R. Civ. P. 56(c)

STATEMENT OF THE CASE

Dr. Robert M. Sinskey, a prominent ophthalmologic surgeon (CR 561-585), charged defendant and respondent Pharmacia Ophthalmics, Inc. ("Pharmacia") with infringement of U.S. Patent No. 4,601,720 (the "Sinskey Patent"). The Sinskey Patent relates to an intraocular lens which is surgically implanted into the eye of a patient to replace the natural lens of the eye.

A complaint was filed in the Central District of California on February 20, 1990 alleging patent infringement.[1] On April 29, 1991, Pharmacia filed a motion for summary judgment asserting that some of the claims of the Sinskey Patent were invalid under 35 U.S.C. § 102(b) because the subject matter of those claims was in public use and on sale more than one year before the filing date of the application.[2] Dr. Sinskey contended that his activities occurring prior to the critical date were experimental, and therefore, the patent claims were valid. After full briefing and oral argument, the trial court granted Pharmacia's motion in an Order for Judgment entered July 16, 1991 (A15) and the Order was filed on September 13, 1991. (A13) Thereafter, the remaining issues in the case were resolved by an Order on Defendant's Motion for Summary Judgment entered January 15, 1992. (A31) The case was then appealed to the Court of Appeals for the Federal Circuit which affirmed the district court's decision on December 28, 1992. (A1; A30)

Intraocular lenses have a central optic portion which serves as the lens, and loops made of thin plastic which hold the lens in place inside the eye. Dr. Sinskey's invention was a new intraocular lens design; he changed the shape of the intraocular lens to make them safer for the patient and easier for the doctor to implant. (A4) Other than the change in shape, the lens was essentially the

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[1] Jurisdiction for a patent infringement claim is original with the district court under 28 U.S.C. § 1338.

[2] The date one year prior to the filing date of a patent application is referred to as "the critical date." In this case the critical date is February 24, 1980.

same as previous lenses, and was made of the same material as previous lenses. (A17) A drawing of the Sinskey lens design is set forth in the figure below (A16, Fig. 3):

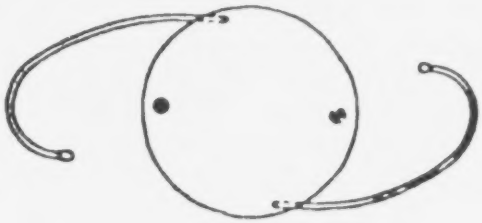

FIG. 3

Once it was commercialized by Iolab Corporation ("Iolab"), Dr. Sinskey's licensee, the shape was adopted by many different manufacturers, including the defendant Pharmacia.

Dr. Sinskey designed his lens in the Fall of 1979, tested it in January and February, 1980 (A16) and filed his patent application in February, 1981. The Sinskey patent issued in July, 1986.

During the course of discovery in the case, it was determined that prior to the critical date of the application for the Sinskey patent, a total of eight intraocular lenses falling within the scope of several claims of the Sinskey patent were implanted by Dr. Sinskey in his patients, and of those 8, some had been sold by Iolab to Dr. Sinskey's patients. (A4-5) Dr. Sinskey charged his normal surgical fee. He examined the patients in routine post-surgical follow-ups. (A11) During a three week period following the critical date, Dr. Sinskey implanted another 3 lenses. About three weeks *after* the critical date,

the lenses were commercially released by Iolab, at which time sales to other doctors and hospitals ensued, and about 3,400 lenses were sold during the first year. (A5)

Also during discovery, Dr. Sinskey's deposition was taken, and he was asked whether he tested the lenses. During an exchange between Dr. Sinskey and the deposing attorney, Dr. Sinskey indicated that he did not test the lenses, and they did not require testing,[3] but the test of these lenses was to implant them in a patient's eye to see if they would be safer and easier to implant:

> . . . the whole key to these whole things was to determine whether this lens was an easy lens to put in or not, than the other lens. Whether it was going to cause the same problems as the other lenses. *The only way you can tell that is by putting them in.*

---

[3] Q: Were there any animal tests after they were sterilized?

A: Not that I remember.

Q: You didn't indicate that they had to be tested?

A: No.

Q: In any way?

A: No. It looked pretty obvious to me what should be done.

Q: What was it obvious that had to be done?

A: I thought it was great myself and I couldn't wait to put them in people.

Q: You knew they were going to work right away, didn't you?

A: Right.

Q: So you didn't feel they had to do any running of tests?

A: No because it was basically - it wasn't that markedly different. . . .

(Appeals Court Appendix,[4] p. 409, Emphasis added.) He further testified: "Well, when I put it in his eye, that's the test." (ACA p. 404).

In response to a motion for summary judgment, Dr. Sinskey stated in his declaration that the testing by implantation was necessary to be sure that the loops were stiff enough to support the lenses, but not too stiff to rupture the position of the eye in which the lens is placed.[5]

It is apparent to most that what Dr. Sinskey was saying was that no special testing of the material used in the lenses was required – it was the same material that had been used for intraocular lenses previously. No *other* testing was required because Dr. Sinskey was performing all of the tests himself.

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[4] Appeals Court Appendix shall be abbreviated ACA

[5] "From the initial time that I conceived my lens, I was quite certain that if my lens was implanted without rupturing the zonules or capsule and did not, for any other reason, cause a 'sunset syndrome,' it would work at least as well as a Shearing lens. However, I recognized that it would be necessary to implant the lenses in a number of patients before I could be sure that the lens reduced the probability of rupturing zonules or capsule during implantation, since in many instances no such rupturing occurs during the implantation of a Shearing lens. I also recognized that because the loops in my new lens were more flexible than those in a Shearing lens, it was possible that the loops would not support the lens properly even if the zonules were not ruptured during implantation." (ACA p. 557-558)

Also in opposing the summary judgment motion, a declaration of Victor Zafra was filed, who was the Assistant Director, and then the Acting Director, of the Bureau of Medical Devices (which includes intraocular lenses) of the Food and Drug Administration from 1978 through 1982. Mr. Zafra testified in his declaration that it was his experience and the FDA's policy that in order to determine if intraocular lenses would perform in the manner expected and were safe for their intended purpose, it was necessary to implant the lenses in the eyes of actual patients. Also he testified that under FDA regulations during the 1980 time frame, the implantation of as few as eight lenses of any new design of an intraocular lens would be considered experimental. (ACA p. 594)

Notwithstanding the foregoing evidence, the court of appeals ruled that the Sinskey declaration conflicted with the Sinskey deposition, and therefore it was proper to disregard the declaration (and apparently to ignore the favorable deposition testimony).[6] Dr. Sinskey asserts that there is no conflict between his deposition and declaration and that because of their content, a genuine issue of material fact existed, precluding summary judgment. Also, the court of appeals ignored Mr. Zafra's testimony altogether. Additionally, the decisions of the district court and court of appeals required "fact finding" in determining that there was a conflict in the testimony, and by

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[6] The court of appeals ruled: "To allow him to preclude summary judgment by contradicting his own prior statements would seriously impair the utility of Federal Rule of Civil Procedure 56. The trial court properly disregarded the declaration in assessing the existence of a genuine issue of fact." (A8)

resolving the alleged conflict in favor of the respondent, the courts failed to abide by the rules of law in summary judgments that all evidence must be viewed in a light most favorable to the non-moving party, and all reasonable inferences must be drawn in favor of the non-moving party.

The court of appeals also ruled that the declaration testimony could be discounted altogether because it was not contemporaneous with the experimentation.

> "Post-hoc affidavit testimony alone, years after the events described and purporting to show an inventor's subjective experimental intent, will never satisfy the burden of establishing experimental use in a case like this where there is not contemporaneous evidence of experimental purpose and the objective evidence is to the contrary."

(A10)

This conclusion by the court of appeals is a clear abandonment of the requirements promulgated by this Court in *Anderson v. Liberty Lobby*, because by ruling that certain evidence can be *ignored* or *disregarded*, the court of appeals and the district court are ignoring genuine issues of material fact. As a result, a party's right to take this case to a jury has been prevented unfairly.

REASONS FOR GRANTING THE WRIT

I. THE COURT OF APPEALS DECISION UNDERMINES THE PRINCIPALS OF ANDERSON V. LIBERTY LOBBY

Fed. R. Civ. P. 56 is clear. It says that summary judgment should not be granted unless there are *no* "genuine issues of material fact" in dispute. So when a party raises genuine issues of material fact, it is only fair to assume that summary judgment should be denied. But that's not what happened in this case. Summary judgment was granted.

The basis for the granting of summary judgment was predicated on the assumption by the Federal Circuit that certain types of testimony and evidence could be ignored. The court of appeals found a conflict between certain declaration testimony and certain deposition testimony of the same witness, when, in fact, there was no conflict. The court of appeals, putting form over substance, took some testimony out of context, and then ignored all other testimony inconsistent with the evidence which did not support their decision.

As indicated above, the appeals court authorized a general rule that non-contemporaneous evidence of experimental use could never withstand a summary judgment motion.

This holding makes little sense, and is an extremely harsh *post facto* ruling for a sole inventor, who at the time of his creation, does not know, and does not abide by the rules created twelve years later.

There is extensive case law holding that in a summary judgment proceeding, the trial court must view the evidence in a light most favorable to the non-moving party, and draw all reasonable inferences in favor of the non-moving party. *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 158-159, 90 S.Ct. 1598, 1608-9 (1970). Disregarding conflicting testimony clearly violates this principal, because taking most testimony in a light most favorable to the non-moving party means giving fair consideration to the opposing testimony – not ignoring it.

The purpose of Rule 56 is to avoid an unnecessary trial, but it is not intended to substitute for trial when it is necessary to find material facts. *Meyers v. Brooks Shoe, Inc.*, 912 F.2d 1459, 1461 (Fed. Cir. 1990). A factual question is material and should be reserved for trial if a reasonable jury could find for the non-moving party based at least in part on its determination of the factual questions. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S.Ct. 2505, 2510, 91 L.Ed. 2d 202 (1986).

In order to provide Dr. Sinskey with a full and fair opportunity to get his case to a jury, it is important to reverse this case and modify the law to prevent the lower courts from ignoring relevant evidence.

II. THERE IS A DISPARITY IN THE CIRCUITS ON WHETHER INCONSISTENT TESTIMONY CAN RAISE A GENUINE ISSUE OF MATERIAL FACT, AND THE BETTER RULE IS TO DENY SUMMARY JUDGMENT UNLESS THE INCONSISTENCY IS A SHAM

The 5th Circuit, in the well reasoned decision of *Kennett-Murray Corp. v. Bone*, 622 F.2d 887 (5th Cir. 1980), has held that:

> In considering a motion for summary judgment, a district court must consider all the evidence before it and cannot disregard a party's affidavit merely because it conflicts to some degree with an earlier deposition. . . . Thus, a genuine issue can exist by virtue of a party's affidavit even if it conflicts with earlier testimony in the party's deposition. (Citations omitted).

Id. at 893. (See also 6 – Pt. 2 Moore's Federal Practice ¶ 56.15[4], p. 56-296; *Dibidale of Louisiana, Inc. v. American Bank & Trust Co.*, 916 F.2d 300 (5th Cir. 1990)). The case went on to analyze the law, noting a discrepancy in the circuits, and the 5th Circuit came to the conclusion that unless the conflicting testimony is a sham, which is not a legitimate issue in this case, the evidence should be weighed by a jury, and summary judgment was improper.

In *Dibidale*, the 5th Circuit vacated a district court grant of summary judgment, where the district court ruled that it could ignore inconsistent declaration testimony. The court went on to hold that the testimony was not necessarily inconsistent with some earlier testimony when the evidence was considered in a light most favorable to a non-moving party.

In the present case, and in the Federal Circuit's current practice, the Federal Circuit authorized disregarding Dr. Sinskey's declaration in assessing whether there was a genuine issue of material fact in dispute. This treatment of Dr. Sinskey's testimony was contrary to the rule of law in the 5th Circuit, which is the better, and more well-reasoned law in the present set of circumstances than a blanket rule which ignores and disregards important testimony.

III. THE FEDERAL CIRCUIT FAILED TO FOLLOW ITS OWN HOLDING IN T.P. LABORATORIES, AND IS NO LONGER FOLLOWING THIS COURT'S HOLDING IN CITY OF ELIZABETH REGARDING EXPERIMENTAL USE

Public use or sale of an invention more than one year before a patent application is filed on the invention renders the patent invalid. 35 U.S.C. § 102(b). However, experimental use is not a public use under 102(b), and thus is not a bar to patentability. It has been established black letter law for more than 100 years that use by an inventor prior to the time he files his patent application is not a bar to patentability if that use is for experimental purposes to bring his invention to perfection. *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126, 24 L.Ed. 1000 (1877).

A leading Federal Circuit case on this issue is *T.P. Laboratories v. Professional Positioners, Inc.*, 724 F.2d 965 (Fed. Cir. 1984), in which the Federal Circuit held that experimental use is *not* public use at all, as that term is used in section 102(b). The rationale and guidelines for experimental use were explained in *Baker Oil Tools, Inc. v. Geo Vann, Inc.*, 828 F.2d 1558 (Fed. Cir. 1987):

> The law recognizes an inventor's need to test the invention, to ascertain whether the work is complete or further change should be made, and to show that the invention will work for its intended purpose. The law further recognizes that such testing and development may encompass or even require disclosure to the public, without barring the inventor's access to the patent system.

The facts in *T.P. Laboratories* were remarkably similar to the facts in this action. There, the patented subject matter was an orthodontic device which a patient would wear to straighten the teeth without the necessity of the patient exerting constant jaw pressure. The dentist who invented the device first conceived of it and made a first prototype in 1956. During the next several years, he prescribed the device for at least three patients prior to the critical date before he filed his patent application in 1962. There was no agreement of confidentiality with the patients. In most instances, he charged his normal fee for professional services for the treatment.

In reversing a trial court holding that these activities constituted a bar to patentability under section 102(b), the Federal Circuit set forth the objective tests for determining whether such use was experimental stating:

> The length of the test period is merely a piece of evidence to add to the evidentiary scale. The same is true with respect to whether payment is made for the device, whether a user agreed to use secretly, whether records were kept of progress, whether persons other than the inventor conducted the asserted experiments, how many tests were conducted, how long the testing period was in relationship to tests of other similar devices. In other words, a decision on whether there has been a "public use" can only be made upon consideration of the entire surrounding circumstances.

724 F.2d at 971-72.

The test factors have more recently been set out by the Federal Circuit in *Baker Oil Tools* as follows:

> In determining whether a public use or sale was under circumstances "substantially for purposes of experiment," courts have considered various factors, such as the necessity for the public testing, the amount of control retained over the operation, the extent of public testing in relation to the nature of the invention, the length of the test period, whether any payment was made, whether there was a secrecy obligation, whether progress records were kept, who conducted the experiments, and the degree of commercial exploitation during the tests in relation to the purpose of the experimentation.

Baker Oil Tools, Inc., 828 F.2d at 1564.

Comparing the Sinskey case to the *T.P. Laboratories* case, the analysis and results should have coincided, which is why it was inconsistent for the Federal Circuit to have ruled differently in the Sinskey case than in the *T.P. Laboratories* case. On the length of the test period, *T.P. Laboratories* test period was 6 years, and in the Sinskey case it was about 2 months.

Regarding the factor of whether payment is made for the device, both in *T.P. Laboratories* and the present case, the doctors charged their usual fees. In the Sinskey case, 3 lenses were charged for, but in *T.P. Laboratories*, it was acknowledged that the orthodontists typically did not charge for the products.

Regarding the factor of whether a user agreed to secrecy, the facts are similar in both cases, and in fact it is slightly more likely for the public to see an orthodontic device in mouth, than an intraocular lens implanted inside an eye.

On the issue of record keeping, both Dr. Sinskey and the doctor in the *T.P. Laboratories* case kept their standard medical records, although there was some indication that one prototype orthodontic device was stored in a box labeled "experimental wires." There were also some notes in patient files indicating the inventor's assessment of the results, but it is not clear whether these were standard medical notes.

On the issue of whether persons other than the inventor conducted the asserted experiments, in both cases the inventor conducted the experiments.

On the number of tests which were conducted, Dr. Sinskey had 11, including 8 before the critical date, and in *T.P. Laboratories*, there were 3 tests.

On the length of the testing period in relationship to tests of other similar devices, there was no information in the *T.P. Laboratories* case about this issue, and Dr. Sinskey had evidence from an FDA expert to support his assertion that 2 months and 11 lenses was experimental.

On the issue of the degree of commercial exploitation during the tests in relation to the purpose of the experimentation, which comes from the Baker case, there was no commercial exploitation in either case until after the critical date in both Dr. Sinskey's case and in *T.P. Laboratories*. In Dr. Sinskey's case, commercial exploitation started about 3 weeks after the critical date when his lens was introduced by Iolab at a trade show.

As the Federal Circuit stated in *Baker Oil Tools*: "The circumstances of payment, it is well established, are factors to be weighed, but payment does not *per se* make a

section 102(b) bar." 828 F.2d at 1564. And in *Armco, Inc., v. Cyclops Corp.* 791 F.2d 147, 151 (Fed Cir. 1986) the Federal Circuit held that although Armco charged and received payment, evidence suggested that it was customary to charge for experimental samples, and therefore, the trial court erred in failing to see a material dispute as to whether the samples were sold for commercial or experimental purposes.

Dr. Sinskey, like most ophthalmologists, but unlike inventors in other fields, lacked the facilities and expertise to make sterile and implantable intraocular lenses. The sophisticated equipment needed to make such devices is found only in the intraocular lens manufacturing facilities. Why should such manufacturers not charge an inventor-ophthalmologist who requests a special lens for experimental purposes?

Finally, several policy issues need to be addressed. Is it more important to support a policy of permitting adequate testing of medical devices and the like, or should the courts be able to rule as a matter of law, without rebuttal, that a single test, or several tests (less than eight) are sufficient to terminate a test period?

Are the courts in a position to substitute their judgment as a matter of law regarding adequate testing for those of a doctor most familiar with a product, and the FDA official in charge of determining the extent of requisite testing?

Thus, under the circumstances of this case, a certiorari is earnestly requested to review the court of appeals decision affirming summary judgment that the subject invention was "on sale" or in public use prior to

the critical date should be reversed. The conclusion of the court of appeals was in violation of the law set forth in *City of Elizabeth* in that Dr. Sinskey was not ~~permitted~~ a reasonable period of time to test his invention.

CONCLUSION

For each of the foregoing reasons, a writ of certiorari should be granted.

Respectfully submitted,

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UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

92-1216

ROBERT M. SINSKEY,

Plaintiff-Appellant,

v.

PHARMACIA OPHTHALMICS, INC.,

Defendant-Appellee.

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David J. Oldenkamp, Poms, Smith, Lande & Rose, of Los Angeles, California, argued for defendant-appellee. With him on the brief were *William Poms* and *Brian W. Kasell*. Also on the brief was *Robert Stier, Jr.*, Bernstein, Shur, Sawyer & Nelson, of Portland, Maine.

Appealed from: U.S. District Court for the Central District of California

Judge Gadbois, Jr.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

92-1216

ROBERT M. SINSKEY,

Plaintiff-Appellant,

v.

PHARMACIA OPHTHALMICS, INC.,

Defendant-Appellee.

DECIDED: December 28, 1992

Before ARCHER, MAYER and MICHEL, *Circuit Judges.*

MAYER, *Circuit Judge.*

Robert M. Sinskey appeals the judgment of the United States District Court for the Central District of California holding that United States Patent No. 4,601,720 is invalid under 35 U.S.C. § 102(b). Because we agree with the district court that Sinskey has not raised a genuine issue as to any material fact and that Pharmacia Ophthalmics, Inc. is entitled to judgment as a matter of law, we affirm.

Background

Dr. Robert M. Sinskey is the named inventor and sole owner of the patent in suit, United States Patent No. 4,601,720 (the '720 patent). On February 20, 1990, Sinskey filed a complaint alleging infringement of the '720 patent by Pharmacia Ophthalmics, Inc. Pharmacia filed a motion

for summary judgment on April 29, 1991, asserting that claims 1, 5 and 6 of the '720 patent were invalid under 35 U.S.C. § 102(b) based upon the public use and sale of the claimed invention by Sinskey and IOLAB Corporation. Sinskey had filed his patent application on February 24, 1981, making the critical date for the use and sale inquiry February 24, 1980. In opposing the motion, he asserted that all pre-critical date activity was for experimental purposes and could not be the basis for a bar under section 102(b). In a July 16, 1991, order, the district court granted summary judgment, holding that Sinskey raised no genuine issue of material fact about the defense of experimental use. This is his appeal of that order.[1]

The patent is directed to an intraocular lens (IOL). IOL's are commonly implanted in the human eye to restore or improve the vision of patients who have had their natural lens removed because of damage or disease. An IOL consists of a transparent lens several millimeters in diameter, and loops or "haptics" joined to the lens. The loops retain the lens in the proper position in the eye.

In 1977, an IOL invented by Dr. Stephen P. Shearing became available. This lens is commonly referred to as the "Shearing" or "J-Loop" lens. Sinskey implanted approximately 1,000 Shearing lenses between 1977 and

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[1] In another order dated January 15, 1992, the district court granted Pharmacia summary judgment, holding that claims 2, 3 and 4 of the '720 patent were invalid under 35 U.S.C. § 103 as obvious in light of the prior art, including Sinskey's and IOLAB's pre-critical date activity. Sinskey has conceded that if we affirm the July 16 order that this activity was not experimental use, and therefore was prior art under section 102(b), then claims 2-4 are invalid under section 103.

1979. The Shearing lens was manufactured and sold by IOLAB as its Model 101 lens. Another IOL available in the late 1970's was designed by Dr. William Simcoe. The "Simcoe" lens had continuously curved C-shaped loops. *See generally Shearing v. Iolab Corp.*, 975 F.2d 1541, 24 USPQ2d 1133 (Fed. Cir. 1992) (discussing the state of the IOL art in the 1960's and 1970's and the early work of Dr. Shearing and Dr. Simcoe). Sinskey was also aware of the Simcoe lens, which had softer loops than the Shearing lens, but he never implanted any of them.

Sinskey testified under oath in a deposition on January 10, 1991, that he saw problems with the prior art IOL's. Specifically, there was a risk of injury due to the loops of the lens piercing the interior of the patient's eye during implantation. Sinskey sought to solve this problem by attempting a compromise between the Shearing J-Loop and the Simcoe C-Loop lenses. In November of 1979, he first thought of using a modified J-loop, having a shape somewhere between those of the other two lens designs. He presented his idea to IOLAB, who had its engineers prepare an engineering drawing of the lens. The lens was designated Model 103J and was added to IOLAB's existing collection of lenses on November 16, 1979. Sinskey has admitted that the Model 103J lens is the invention of claims 1, 5 and 6 of the '720 patent. By late December, 1979, IOLAB produced the first sterile Model 103J lenses which were ready for implantation into patients. IOLAB made the Model 103J lenses in the same way and with the same materials as the Shearing Model 101 lenses.

Sinskey first successfully implanted the Model 103J lens into a patient's eye on January 17, 1980, and between

February 7 and 18, 1980, he implanted seven more Model 103J lenses in seven additional patients. Thus, a total of eight Model 103J lenses were implanted prior to February 24, 1980, the critical date. All eight implantations took place at St. John's Hospital, Santa Monica, California, under normal conditions and following standard hospital procedures.

IOLAB's computerized record summaries show that IOLAB sold Sinskey at least three separate Model 103J lenses, pursuant to an invoice dated January 18, 1980. The records show the lenses were sold for $250 apiece and payment was received in full. IOLAB sales records also show that three Model 103J lenses were ordered on January 15, 1980, and that one of the lenses was shipped February 11, 1980, and invoiced for $250 on February 12, 1980. Another IOLAB sales document indicates that Sinskey ordered 25 Model 103J lenses on February 19, 1980.

On March 17, 1980, after Sinskey implanted three more Model 103J lenses, for a total of eleven, IOLAB first offered the Model 103J lens for sale commercially to other ophthalmologists. IOLAB continued to sell Model 103J lenses for $250 each, with over 3,400 sold between March 17, 1980, and March 27, 1981.

Discussion

The first question is the propriety of summary judgment which we decide for ourselves. We are not bound by the district court's ruling that there was no genuine issue of material fact to prevent judgment for Pharmacia as a matter of law. *Armco, Inc. v. Cyclops Corp.*, 791 F.2d 147, 149, 229 USPQ 721, 723 (Fed. Cir. 1986).

The facts set out above are not in dispute. The only issue is the purpose for which the pre-critical date implantations were made. The burden was on Sinskey to present some evidence that would raise a genuine issue of material fact over his allegation of experimental use. He argued that his declaration in opposition to defendant's motion for summary judgment does that. The district court agreed that the declaration was in direct conflict with Sinskey's previous testimony at the deposition, but held that this conflict did not raise a genuine issue of material fact.

Sinskey had testified under oath in the deposition that no testing of the Model 103J lens was required.[2] He made statements to the effect that he believed the lens

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[2] The particular portion of Sinskey's deposition relied upon by the district court reads as follows:

Q. Were there any animal tests after they were sterilized?
A.Not that I remember.
Q.You didn't indicate that they had to be tested?
A.No.
Q.In any way?
A.No, it looked pretty obvious to me what should be done.
Q.What was it obvious that had to be done?
A.I thought it was great myself and I couldn't wait to put them in people.
Q.You knew they were going to work right away, didn't you?
A.Right.
Q.So you didn't feel they had to do any running of tests?
A.No, because it was basically – it wasn't that markedly different . . .

would work and that the lens was not significantly different from the Shearing lens which he had implanted on hundreds of occasions in the past. And he testified that, after the first implantation, he felt sure the Model 103J lens would work and that there was no need for any further tests.

In the declaration, on the other hand, Sinskey said he considered the first eleven implants of the Model 103J lens to be experimental.[3] These assertions directly conflict with the deposition statements that he did not believe the lens required testing. There is no explanation for the facial inconsistency, and the declaration does not attempt to reconcile the conflict; indeed, it does not address Sinskey's deposition testimony at all.

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[3] Discussing the first implantation Sinskey stated in the declaration:

> While I was satisfied with the performance of the lens in this particular implantation, I still could not be sure that the lens was going to work in all implantation surgeries. . . . I therefore needed to perform additional tests in order to insure that the lens would consistently work well. . . .

Referring to the first eleven implantations, he said,

> I considered those eleven implantations . . . to be experimental. I wanted to determine whether my new lens design would be easier and safer to implant than the Shearing lens and whether it would minimize the risk of damage to the zonules and capsule. In order to accomplish this test, I knew I would have to implant the lenses in a number of patients. . . . It was only after these eleven implantations were successfully completed that I would be sure that my new design both minimized the risk of zonular and capsular damage while still providing sufficient support for the lens.

A party cannot create an issue of fact by supplying an affidavit contradicting his prior deposition testimony, without explaining the contradiction or attempting to resolve the disparity. *See e.g., Martin v. Merrell Dow Pharmaceuticals, Inc.*, 851 F.2d 703, 706 (3d Cir. 1988); *Mack v. United States*, 814 F.2d 120, 124 (2d Cir. 1987); *Franks v. Nimmo*, 796 F.2d 1230, 1237 (10th Cir. 1986). Where, as here, a party has been examined extensively at deposition and then seeks to create an issue of fact through a later, inconsistent declaration, he has the duty to provide a satisfactory explanation for the discrepancy at the time the declaration is filed. To allow him to preclude summary judgment simply by contradicting his own prior statements would seriously impair the utility of Federal Rule of Civil Procedure 56. the trial court properly disregarded the declaration in assessing the existence of a genuine issue of fact.

The statutory presumption of validity under 35 U.S.C. § 282 puts the burden of proving invalidity on the party asserting it and the burden never shifts to the patentee. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1534, 218 USPQ 871, 875 (Fed. Cir. 1983). But where experimental use is raised to defeat a claim of anticipation under 35 U.S.C. § 102(b), the patentee is not wholly relieved of obligation. According to *T.P. Laboratories, Inc. v. Professional Positioners, Inc.*, 724 F.2d 965, 971, 220 USPQ 577, 582 (Fed. Cir. 1984), the court must look to the totality of the circumstances to determine whether there has been a public use within the meaning of section 102(b). On summary judgment, once an alleged infringer has presented facts sufficient to establish a *prima facie* case of public use, it falls to the patent owner to come

forward with some evidence to the contrary sufficient to raise a genuine issue of material fact. *Harrington Mfg. Co. v. Powell Mfg. Co.*, 815 F.2d 1478, 1480, 2 USPQ2d 1364, 1367 (Fed. Cir. 1986).

Pharmacia has put forth evidence establishing the eight pre-critical date implantations and the sale by IOLAB of at least three Sinskey lenses. Sinskey did not contest these facts; in fact, he admitted them in Pharmacia's initial request for admissions. Pharmacia has thus met its burden of establishing a *prima facie* case of invalidity under section 102(b) because the patented lenses were in public use or on sale more than one year before the patent application was filed. It was then incumbent on Sinskey to put forth some evidence in rebuttal to support his claim of experimental purpose.

To establish that an otherwise public use or sale does not run afoul of section 102(b), it must be shown that the activity was "substantially for purposes of experiment." *Baker Oil Tools, Inc. v. Geo Vann. Inc.*, 828 F.2d 1558, 1564, 4 USPQ2d 1210, 1214 (Fed. Cir. 1987). Objective evidence such as the length of the test period, whether payment was made for the device, whether there was a secrecy agreement, whether progress reports were kept, whether someone other than the inventor conducted the experiments, and the overall number of tests may be considered. *See T.P. Laboratories*, 724 F.2d at 971, 220 USPQ at 582.

As we have seen, Sinskey's only rebuttal evidence was the declaration in opposition to summary judgment proclaiming that the implantations were intended to be experimental, which was inconsistent with his deposition

statement that he did not believe the lens needed to be tested. Sinskey argues here that his deposition is not inconsistent with his later declaration. He says that together they raise a genuine issue of material fact with regard to the alleged experimental purposes of the pre-critical date implantations. Sinskey argues that the implantations themselves were the required tests, and that he was never asked at deposition the purpose of the implantations, or how many would be necessary before he would be satisfied the lens was safe and effective. Even if the declaration could somehow be interpreted as consistent with the deposition, however, Sinskey still could not forestall summary judgment because after-the-fact testimony of an investor's subjective "experimental intent" is entitled to minimal weight. *In re Smith*, 714 F.2d 1127, 1135, 218 USPQ 976, 983 (Fed. Cir. 1983). "[I]f a mere allegation of experimental intent were sufficient, there would rarely if ever be room for summary judgment based on a true 'on sale' defense under 35 U.S.C. § 102(b)." *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1150, 219 USPQ 13, 17 (Fed. Cir. 1983). Besides, both his deposition and his declaration occurred more than a decade after the activities at issue. Post-hoc affidavit testimony alone, years after the events described and purporting to show an inventor's subjective experimental intent, will never satisfy the burden of establishing experimental use in a case like this were there is no contemporaneous evidence of experimental purpose and the objective evidence is to the contrary. *See Harrington Mfg. Co.*, 815 F.2d at 1481 n.3, 2 USPQ2d at 1366 n.3

The objective evidence in this case cuts heavily against experimental use. Sinskey charged his usual

surgical fee of $1,900 for each of the eight operations and IOLAB charged its standard $250 price for the lenses. He did not inform the patients that they were being treated with a "new" or "experimental" lens, nor did he obtain any kind of secrecy agreement from the patients or surgical staff. None of the documents provided by IOLAB or Sinskey ever referred to the Model 103J as "experimental" or the subject of tests. Apparently routine medical records of these implantations were kept, but Sinskey does not refer to them specifically, and they were not put before the district court. If they contained any indication that the implantations were part of an experimental or test program, rather than routine operations, it is fair to assume Sinskey would have offered them. Besides, in its Pre-market Approval Application to the FDA, IOLAB characterized the Sinskey lens as "equivalent in design, use and function to the Shearing . . . Lenses" and requested that it be "approved at this time as a supplement to the Shearing" lenses.

Sinskey also provided no evidence contemporaneous with the initial eight implant operations that would corroborate his claims that they were for experimental purposes. Even evidence of his subjective intent at the time of the implantations was absent from the record. It is logical to expect that if an inventor set out to test a new device, there would be some contemporaneous evidence about the success or at least the occurrence of the tests. One would expect some note at the time that the test was, or was not, successful. In an invention that was part of a medical procedure, the inventor might have made some notation in the medical records about the use of the

experimental device. Here there was no contemporaneous evidence at all, subjective or otherwise, that might indicate the existence of tests or an experimental program. Nothing else Sinskey raises persuades us an error was committed.

Conclusion

Accordingly, the judgment of the United States District Court for the Central District of California is affirmed.

AFFIRMED

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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

ROBERT M. SINSKEY, an individual, Plaintiff, v. PHARMACIA OPHTHALMICS, INC. a California corporation, Defendant.	**CASE NO. 90 0581 RG (Kx)** **ORDER** (Filed Sep. 13, 1991)

I. FINDINGS OF FACT AND CONCLUSIONS OF LAW

Pending before this Court is Defendants' Motion for Summary Judgment, seeking to declare claims 1, 5 and 6 of the U.S. Patent No. 4,601,720 (the '720 patent) are invalid under 35 U.S.C. § 102(b). Having considered this motion, the submissions of the parties, the arguments of counsel in open court on June 3, 1991, and the applicable

law, the Court grants Defendant's motion, and finds claims 1, 5 and 6 invalid.

II. INTRODUCTION

Plaintiff Dr. Robert Sinskey (Sinskey) is the named inventor and sole owner of the '720 patent. On February 20, 1990, Sinskey filed a Complaint alleging infringement of the '720 patent by Pharmacia Ophthalmics Inc. (Pharmacia). On March 15, 1990, Pharmacia answered and counterclaimed alleging, among other things, that the '720 patent was invalid pursuant to 35 U.S.C. § 102(b).

The present Motion for Summary Judgment was filed by Pharmacia on April 29, 1991. The motion asserts that claims 1, 5 and 6 of the '720 patent are invalid under 35 U.S.C. § 102(b) based upon the public use and sale of the claimed invention by Sinskey and Iolab Corporation (IOLAB) more than one year before Sinskey filed his patent application.

Any of the following findings of fact which may be deemed a conclusion of law are hereby incorporated into the Conclusions of Law, and any of the following conclusions of law which may be deemed a finding of fact are hereby incorporated into the Findings of Fact.

III. FINDINGS OF FACT

a. Development of the Model 103J IOL

1. Intraocular lenses (IOL's) are commonly implanted in human eyes to restore or improve vision

after the removal of cataracts. An IOL is a small transparent optical lens which is several millimeters in diameter. The IOL includes loops which are attached to and extend from the lens. The loops are provided to retain the lens in the proper position in the eye.

2. An IOL which became available in 1977 had loops that were designed by Dr. Stephen P. Shearing. This IOL was commonly known as the Shearing or J-loop and is shown in FIG. 1. The J-loop lens was manufactured and sold by IOLAB as its Model 101 lens.

FIG. 1

3. Sinskey began implanting the J-loop lens in 1977 and by the end of 1979 he had implanted over 1000 of the J-loop lenses. Sinskey found the J-shaped loops of the Model 101 lens to be relatively stiff, which sometimes made them difficult to implant.

4. Another IOL available in the late 1970's had loops which were designed by Dr. William Simcoe. This particular IOL, commonly known as the C-loop lens, is shown in FIG. 2. Sinskey was aware of the C-loop lens, which had loops that were softer than the Model 101 J-loops. However, Sinskey never implanted the C-loop lens in a patient.

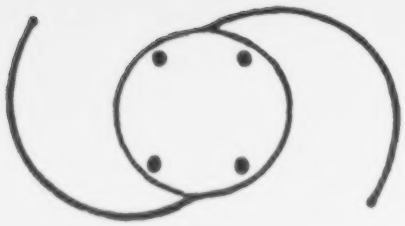

FIG. 2

5. Sinskey testified under oath that he attempted to reach a happy medium between the J-loop and C-loop lenses by using a lens having loops with a shape between the J-loop and the C-loop. Sinskey testified that he first conceived of this modified J-loop design in the Fall of 1979 and presented his idea to Peter LeHay, then President of IOLAB, at that time. Within days, Mr. LeHay had engineers at IOLAB prepare an engineering drawing of the lens. That lens, which is shown in FIG. 3, was identified as the Model 103J. It was added to IOLAB's existing collection of lenses on November 16, 1979.

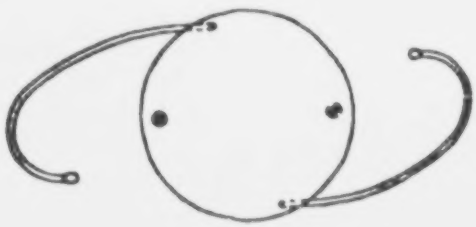

FIG. 3

6. In early December 1979, IOLAB provided Sinskey with non-sterile samples of the Model 103J lens. Sinskey examined the sample lenses and found them satisfactory. By late December, 1979, IOLAB had produced the first

sterilized Model 103J lenses which were ready for implantation into patients. IOLAB made the Model 103J lenses in the same way and with the same materials used for the Shearing Model 101 lenses.

7. Sinskey testified under oath that no testing of the Model 103J was needed, and that he knew even before implantation that the lens would perform well:

Q. Were there any animal tests after they were sterilized?

A. Not that I remember.

Q. You didn't indicate that they had to be tested?

A. No.

Q. In any way?

A. No, it looked pretty obvious to me what should be done.

Q. What was it obvious that had to be done?

A. I thought it was great myself and I couldn't wait to put them in people.

Q. You knew they were going to work right away, didn't you?

A. Right.

Q. So you didn't feel they had to do any running of tests?

A. No, because it was basically – it wasn't that markedly different. . . .

(Sinskey Deposition Transcript. p. 45, line 9 to p. 46, line 3.)

B. Public Use Of The Model 103J IOL

8. Sinskey first successfully implanted his Model 103J lens into a patient's eye on January 17, 1980. The patient was Nick Williams, and the surgery took place at St. John's Hospital, Santa Monica, California. With respect to the first surgery, Sinskey testified that the lens was easy to implant, that he was very pleased with its performance, that it behaved exactly the same way as other lenses after implantation, and that he saw no need to conduct any special tests or measurements.

9. On February 6, 1980, Sinskey implanted three more Model 103J lenses in three different patients. On February 7, 1980, he implanted a Model 103J lens in another patient. On February 15, 1980, he implanted two Model 103J lenses into two more patients. On February 18, 1980, he implanted another Model 103J lens in another patient. Thus, a total of 8 Model 103J lenses were implanted prior to February 24, 1980. All 8 surgical implantations took place in operating rooms at St. Johns Hospital under normal conditions and following standard hospital procedures. Sinskey charged his usual surgical fee of $1,900 for each of the eight operations.

C. Sale Of The Model 103J IOL

10. According to computerized record summaries, IOLAB sold at least three separate Model 103J lenses, pursuant to an invoice dated January 18, 1980. The record summaries show that these three lenses were sold for $250 apiece, and that IOLAB received payment in full for each lens.

11. IOLAB sales records also show that three Model 103J lenses were ordered on January 15, 1980, and that one of the lenses was shipped on February 11, 1980, and invoiced for $250 on February 12, 1980. Another IOLAB sales document shows that 25 Model 103J lenses were ordered by Sinskey on February 19, 1980.

12. After the February 24, 1980 critical date, IOLAB continued to sell the Model 103J lens for $250 each, and sold over 3,400 of the lenses during the period from March 17, 1980 to March 27, 1981.

D. The '720 Patent

13. The '720 patent contains claims 1-6. Sinskey concedes that the Model 103J lens falls within the scope of claims 1, 5 and 6.

IV. CONCLUSIONS OF LAW

1. 35 U.S.C. § 102(b) provides that a person is prevented from obtaining a patent if the invention was "in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States." The critical date for the '720 patent under 24 U.S.C. § 102(b) is February 24, 1980.

2. The determination whether an invention was in public use, sold or on sale under 35 U.S.C. § 102(b) is a question of law which may properly be decided by summary judgment. *Harrington Mfg. Co. v. Powell Mfg. Co.*, 815 F.2d 1478 (Fed. Cir. 1986); *Barmag Barmer Maschinenfabrik A.G. v. Murata Mach., Ltd.*, 731 F.2d 831 (Fed. Cir. 1984);

D.L. Auld Co. v. Chroma Graphics Corp., 714 F.2d 1144 (Fed. Cir. 1983).

3. 35 U.S.C. § 102(b) is intended to preclude attempts by an inventor to profit from commercial use of an invention for more than a year before an application for patent is filed. *D.L. Auld*, 714 F.2d 1147.

4. The defendant, Pharmacia, has the burden of proving by clear and convincing evidence that the invention was either in public use, sold or offered for sale more than one year before the application for the patent. *Buildex Inc. v. Kason Indus., Inc.*, 849 F.2d 1461, 1462-63 (Fed.Cir. 1988). If, however, the defendant carries its burden and shows that the invention was in public use, sold or offered for sale before the critical date, the patent owner must come forward with an explanation of the circumstances surrounding what would otherwise appear to be a commercialization outside the one year grace period. *UMC Electronics Co. v. United States*, 816 F.2d 647, 656 (Fed.Cir. 1987).

5. To defeat a motion for summary judgment, a patentee need not prove an experimental purpose, but must submit facts indicating an ability to come forward with evidence that such proof is possible. *D.L. Auld*, 714 F.2d at 1150. What is required is a showing of sufficient information that would support the existence of the claimed factual dispute and require a judge or jury to resolve the conflicting different versions of truth through a trial. *Harrington*, 815 F.2d at 1480.

6. Here, Pharmacia has met its burden by producing clear and convincing evidence that the Model 103J lens was in public use, sold and offered for sale before the

critical date. Indeed, the implantations, actual sales and orders for other sales of the lenses are undisputed.

7. Sinskey argues, however, that the implantations, sales and offers to sell were experimental, and thus not uses or sales within the meaning of 35 U.S.C. § 102(b). To address that issue, the Court must look to the totality of the circumstances. *Harrington*, 815 F.2d at 1481.

8. Courts have articulated various objective indicia to be considered under the totality of circumstances test, including:

> the necessity for public testing, the amount of control retained over the operation, the extent of public testing in relation to the nature of the invention, the length of the test period, whether any payment was made, whether there was a secrecy obligation, whether progress records were kept, who conducted the experiments, and the degree of commercial exploitation during the test in relation to the purpose of the experimentation.

Baker Oil Tools, Inc. v. Geo Vann, Inc., 828 F.2d 1558, 1564 (Fed.Cir. 1987); *see also, T.P. Laboratories, Inc. v. Professional Positioners, Inc.*, 724 F.2d 965, 972 (Fed.Cir. 1984), *cert. denied*, 469 U.S. 826 (1984). However, not all testing or experimentation may be considered: only that relating to claimed elements of the invention. *Western Marine Electronics v. Furuno Electric Co., Ltd.*, 764 F.2d 840, 847 (Fed.Cir. 1985) ("testing or experimentation performed with respect to non-claimed features of the device does not show that the *invention* was the subject of experimentation").

9. The test for experimental purpose looks to objective factors indicating a reason for such testing and experiment. An inventor's subjective intent is generally of minimal value, *In re Smith*, 714 F.2d 1127, 1135 (Fed.Cir. 1983) (citations omitted), and is considered altogether immaterial when objective evidence points to the contrary. *Harrington*, 815 F.2d at 1481n.3.

10. Here, an examination of all the circumstances according to such objective criteria demonstrates conclusively that Sinskey's activities before the critical date were not experimental according to § 102(b), and Sinskey has failed to produce any material evidence to the contrary.

11. Considering first, for example, the nature of the invention and whether there was a need for any testing, Sinskey's lens was intended to address the problems caused by the stiffness of the loops in the Shearing lens. The flexible loops in Sinskey's lens were inherently less likely to damage tissues in the eye – precisely because they were flexible, not stiff. By their very nature – because "all compression forces contact the loop at an angle, rather than straight down or parallel to the shaft as in the original J loop lenses," Sinskey Decl. ¶ 9 – the modified loops were less likely than the Shearing loops to rupture the surrounding eye tissue. For an experienced surgeon like Sinskey who had implanted over 1000 Shearing lenses, the advantages of the flexible loops were admittedly apparent without further testing. Indeed, Sinskey's conviction that the modified J-loop lenses would work, and his admitted eagerness to implant them in patients, is like the attitude of the inventors in *Branham Industries Inc. v. Hydrafab Inc.*, 11 USPQ 2d 1529, 1531-32

(S.D.Tex. 1989) (found invalid under § 102(b) over inventors' claim of experimental purpose), who were "satisfied that the invention embodied in [the patent] would work for its intended purpose before the patented invention was first placed on sale." In contrast is *Manville Sales Corp. v. Paramount Systems, Inc.*, 917 F.2d 544, 550 (Fed.Cir. 1990), where there was "no basis for confidence by the inventor that the invention would perform as intended, and hence no proven invention to disclose."

12. Similarly, Sinskey does not satisfy other objective criteria of experimental purpose. He produced no evidence of experiments on animals or eye-bank eyes prior to implanting the lenses in actual patients. He did not keep progress records, and does not indicate that he did anything out of the ordinary to evaluate or monitor the patients whose eyes he claims to have used for his "tests." There are no patient records, notes or any other contemporaneous documents indicating an experimental purpose to the earliest implantations.

13. Further, Sinskey charged his normal surgical fee and IOLAB charged their normal sales price for the lenses. Acceptance of normal surgical fees and the payment of regular sales prices suggests that the commercial aspect of the allegedly "experimental" implantations was no different from the previous implantation and sales of the Shearing lens by Dr. Sinskey and IOLAB. Moreover, there is no evidence that Sinskey referred to the implantations as "experiments" at the time, either to his patients or to anyone else. In contrast, *see Manville Sales*, where a contemporaneous memorandum described experimental activities as such and thus helped to negate the inference that "this is a case of a patentee attempting, after the fact,

to portray his earlier actions as experimental use." *Manville Sales*, 917 F.2d at 551.

14. In summary, the objective evidence shows that Sinskey did not carry out a program of experimentation before beginning the commercial exploitation of his modified J-loop lens because he knew from substantial experience that his lenses with more flexible loops would be easier and safer to implant than the Shearing lens then in use. That objective evidence is confirmed and supported by Sinskey's own deposition testimony.

15. To rebut the clear evidence of public use and sale before the critical date, Sinskey proffers his own declaration, and the declaration of Victor Zafra, a former employee of the Food and Drug Administration. Neither declaration raises an issue of material fact requiring a judge or jury to resolve conflicting versions of truth through a trial.

16. In his own declaration, Sinskey claims that the initial eight implantations of the Model 103J were experimental. The expression by an inventor, however, of his subjective intent to experiment, particularly after institution of litigation, is of minimal value. *In re Brigance*, 792 F.2d 1103, 1108 (Fed. Cir. 1986); *TP Laboratories*, 724 F.2d at 972; *In re Smith*, 714 F.2d 1127, 1135 (Fed. Cir. 1983). Furthermore, Sinskey's declaration flatly contradicts his own deposition testimony. A party does not create an issue of fact simply by submitting an affidavit contradicting his own prior testimony. *Foster v. Arcata Associates, Inc.*, 772 F.2d 1453, 1462 (9th Cir. 1985); *Radobenkco v. Automated Equip. Corp.*, 520 F.2d 540, 544 (9th Cir. 1975). The self-serving statements in Sinskey's declaration are

legally immaterial, and cannot overcome the substantial objective evidence to the contrary.

17. The affidavit of Victor Zafra is similarly insufficient to raise a genuine issue of material fact. It simply contains general statements about FDA policy. No connection is made between those general statements and the Mobel 103J lens at issue.

V. CONCLUSION

Based on the foregoing, the Court concludes that there are no genuine issues of fact in dispute and that the invention embodied in claims 1, 5 and 6 of the '720 patent was publicly used, sold and on sale prior to the critical date of February 24, 1980. The Court also concludes that those uses and sales were not for experimental purposes. Accordingly, defendant Pharmacia is entitled to judgment, as a matter of law, that claims 1, 5 and 6 of U.S. Patent No. 4,601,720 are invalid under 35 U.S.C. 102(b).

Dated: 9-13-91

RICHARD A. GADBOIS, JR.
Honorable
Richard A. Gadbois, Jr.
United States
District Court Judge

Presented by:

/s/ David J. Oldenkamp
David J. Oldenkamp, a member of
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Attorneys for Defendant
PHARMACIA OPHTHALMICS, INC.

PROOF OF SERVICE

STATE OF CALIFORNIA)
) ss
COUNTY OF LOS ANGELES)

I am employed in the County of Los Angeles, State of California. I am over the age of 18 years and not a party to the within action. My business address is 2121 Avenue of the Stars, Suite 1400, Los Angeles, California 90067.

On September 11, 1991 I served the attached ORDER on the interested parties in the above action by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid in the United States mail at Los Angeles, California, addressed as follows:

Stanley W. Sokoloff, Esq.
Ronald W. Reagin, Esq.
Stephen D. Gross, Esq.
BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN
12400 Wilshire Blvd., Seventh Floor
Los Angeles, California 90025-1026

[X] **BY MAIL** I caused such envelope with postage thereon fully prepaid to be placed in the United States mail at Los Angeles, California.

[ ] **BY PERSONAL SERVICE** I caused the same to be delivered by hand to the addressee.

Executed on September 11, 1991, at Los Angles, California.

[ ] **STATE** I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

[X] **FEDERAL** I declare that I am employed in the office of a member of the bar of this Court at whose direction the service was made.

/s/ Nancy J. Cedro
Nancy J. Cedro

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

ROBERT M. SINSKEY, an individual, Plaintiff, v. PHARMACIA OPHTHALMICS, INC., a California corporation, Defendant.	)	CASE NO. CV 90-581 RG(Kx) ORDER FOR JUDGMENT (Filed Jul. 15, 1991)

Defendant's motion for summary judgment will be granted. Its prior motion, based on anticipation of the Sinskey device by prior art (Kratz/10L), was denied last year in what was then perceived as an exceptionally close call. The judgment here ordered, under the "public use/on sale" bar of Section 102(b), is not that close.

Defendant has proven a number of uses of the subject device prior to the critical date – February 24, 1980. The plaintiff charged his usual fee for implantation and did no extraordinary follow-up on the patients. He now claims experimental use. The Court's reluctance to reject that position in a medical device case is overcome by the record in favor of the motion and the great paucity of legal evidence to the contrary. The principal decisive factors are:

1. The prior use/sale activity is unquestioned.

2. Analysis under the CAFC criteria for distinguishing experimental and public use comes up almost empty for the plaintiff. (*TP Laboratories*)

3. The evidence rebutting the clear showing of prior public use is only the testimony of the inventor as to his experimental intent and a somewhat general statement by an FDA employee that experiment with such a product is necessary. With regard to the former, subjective intent of the inventor is entitled to little or no weight, and, in any event, his declaration flatly contradicts his deposition testimony. As to the latter, it does not rise to the level of submitting this record to a jury.

Counsel for defendant will file and serve a proposed order expressing in some detail the reasons for this proposed ruling.

/s/ Richard A. Gadbois, Jr.
RICHARD A. GADBOIS, JR.
United States District Judge

DATED: July 15, 1991

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

92-1216

ROBERT M. SINSKEY,

Plaintiff-Appellant,

v.

PHARMACIA OPHTHALMICS, INC.,

Defendant-Appellee.

JUDGMENT

ON APPEAL from the UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF CALIFORNIA

in CASE NO(S). 90-0581

This CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

AFFIRMED

ENTERED BY ORDER OF THE COURT

DATED DEC 28 1992 /s/ Francis X. Gindhart
Francis X. Gindhart, Clerk

ISSUED AS A MANDATE: January 19, 1993

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

ROBERT M. SINSKEY, Plaintiff, v. PHARMACIA OPHTHALMICS, INC., Defendant.	)	CASE NO. 90-0581 RG (Kx) (Filed Jan. 13, 1992)

ORDER ON DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

This action came on for hearing before the Court, Honorable Richard A. Gadbois, Jr., presiding. Having considered the moving and opposition papers, arguments of counsel and all other matters presented, the Court hereby rules as follows:

IT IS HEREBY ADJUDGED THAT Claims 2, 3, and 4 of the United States Patent No. 4,601,720 are invalid as obvious in view of the prior art pursuant to 35 U.S.C. §103. The Court finds that the instant case is not "exceptional" so as to merit an an award of attorney's fees pursuant to 35 U.S.C. §285.

IT IS HEREBY ORDERED THAT:

1. Defendant's Motion for Summary Judgment is granted.

2. Claims 2, 3 and 4 of United States Patent No. 4,601,720 are invalid.

3. Defendant's request for attorney's fees, pursuant to 35 U.S.C. §285, is denied.

4. Defendant's counterclaim for declaratory relief is dismissed as moot.

IT IS SO ORDERED.

RICHARD A. GADBOIS, JR.
RICHARD A. GADBOIS, JR.

DATED: Jan. 13, 1991 [sic]

MOTION FOR LEAVE TO FILE OUT OF TIME
ROBERT M. SINSKEY'S
PETITION FOR REHEARING
AND
SUGGESTION FOR HEARING IN BANC

(Filed Jan. 27, 1993)

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

92-1216

ROBERT M. SINSKEY,

Plaintiff-Appellant,

v.

PHARMACIA OPHTHALMICS, INC.,

Defendant-Appellee.

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA, HONORABLE RICHARD GADBOIS, DISTRICT JUDGE

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The motion is DENIED.

FOR THE COURT,

1/27/93
Date

/s/ Francis X. Gindhart
FRANCIS X. GINDHART
Clerk

STATUTORY PROVISIONS INVOLVED

This case involves the following statutory rules and provisions, which are set out in full below:

35 U.S.C. §102 Conditions for patentability; novelty and loss of right to patent.

A person shall be entitled to a patent unless –

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States,

Rule 56. Summary Judgment.

c) The motion shall be served at least 10 days before the time fixed for hearing. The adverse party prior to the day of hearing may serve opposing affidavits. The judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law. A summary judgment, interlocutory in character, may be rendered on the issue of liability alone although there is a genuine issue as to the amount of damages.

Supreme Court, U.S.

No. 92-1576

In The

Supreme Court of the United States

October Term, 1992

ROBERT M. SINSKEY,

Petitioner,

v.

PHARMACIA OPTHALMICS, INC.,

Respondent.

Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether under Fed. R. Civ. P. 56(c), and the Supreme Court cases interpreting that rule, summary judgment of patent invalidity under 35 U.S.C. § 102(b) is properly granted when *prima facie* and undisputed showings of on-sale and public-use bars have been made, all objective evidence points away from any experimental use of the invention claimed by the patent-in-suit, and the only evidence showing an experimental purpose is the inventor's subjective intent as stated in a declaration made subsequent to and in direct conflict with the inventor's earlier deposition testimony.

LIST OF PARTIES

(SUPREME COURT RULE 29.1)

Pursuant to Supreme Court Rule 29.1, the following is a list of all parent companies and subsidiaries (except wholly-owned subsidiaries) of Respondent Pharmacia Opthalmics, Inc.:

Procordia A.B.

Kabi Pharmacia A.B.

Volvo

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STATEMENT OF THE CASE

Respondent Pharmacia Opthalmics, Inc. ("Pharmacia") incorporates herein by reference the background section contained in the Federal Circuit decision reported at 982 F.2d 494, 25 U.S.P.Q.2d 1290 (Fed. Cir. 1992) and reproduced in the Appendix section of Petitioner Sinskey's Petition for Writ of Certiorari at A 1-12.

REASONS FOR DENYING THE WRIT

The decision of the Court of Appeals for the Federal Circuit affirming the trial court's grant of summary judgment in favor of Pharmacia contains nothing that supports this Court's exercise of its discretion to grant a writ of certiorari: the Federal Circuit's decision is not in conflict with the decisions of any other federal appellate courts, and is totally consistent with the decisions of those courts; no important question of law is raised by the decision, and; the Federal Circuit's decision is not only correct but is fully supported by prior case law. For these reasons, which are explained more fully hereinbelow, Sinskey's petition for a writ of certiorari should be denied.

I. THE CIRCUIT COURTS ARE IN COMPLETE AGREEMENT THAT A GENUINE ISSUE OF MATERIAL FACT IS NOT RAISED WHEN A PARTY CONTRADICTS, WITHOUT SATISFACTORY EXPLANATION, HIS OR HER PRIOR TESTIMONY

Whenever they have considered the question, the courts of appeals have uniformally agreed that no

genuine issue of material fact is raised when, without satisfactory explanation, a party contradicts his or her prior testimony. *See, e.g., Martin v. Merrell Dow Pharmaceuticals, Inc.*, 851 F.2d 703 (3d Cir. 1988); *Franks v. Nimmo*, 796 F.2d 1230 (10th Cir. 1986); *Miller v. A. H. Robins Co.*, 766 F.2d 1102 (7th Cir. 1985); *Van T. Junkins & Assocs. v. United States Indus.*, 736 F.2d 656 (11th Cir. 1984); *Camfield Tires, Inc. v. Michelin Tire Corp.*, 719 F.2d 1361 (8th Cir. 1983); *Radobenko v. Automated Equip. Corp.*, 520 F.2d 540 (9th Cir. 1975); *Perma Research & Dev. Corp. v. Singer Co.*, 410 F.2d 572 (2d Cir. 1969).

The rationale behind these decisions is quite simple: the objective sought by the summary judgment rule "would be seriously impaired if the district court were not free to disregard the conflicting [declaration]." *Martin v. Merrell Dow*, 851 F.2d at 706.

In the present case, the Federal Circuit expressly upheld the district court's finding that the assertions in Sinskey's declaration regarding the alleged experimental purpose behind his first eleven intraocular lens (IOL) implantations "directly conflict with [his] deposition statements that he did not believe the lens required testing." (A 7.)[1] Moreover, the Federal Circuit stated that "[t]here is no explanation for the facial inconsistency, and the declaration does not attempt to reconcile the conflict; indeed, it does not address Sinskey's deposition testimony at all." (A 7.) Under such circumstances, and given the uniform position of the circuit courts on this issue, the

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[1] Unless otherwise stated, appendix references are to the appendix appearing at the end of Sinskey's Petition for Writ of Certiorari.

Federal Circuit was obviously justified in holding that Sinskey had failed to meet his burden of showing the existence of a genuine issue of material fact. To hold otherwise would, as the Federal Circuit stated "allow [Sinskey] to preclude summary judgment simply by contradicting his own prior statements." (A 8.)

Nothing in the Federal Circuit's decision is in conflict with the decisions of other circuits that have addressed this issue. Moreover, no case cited by Sinskey demonstrates that such a conflict exists.

Specifically, *Kennett-Murray Corp. v. Bone*, 622 F.2d 887 (5th Cir. 1980), the principle case relied on by Sinskey, expressly recognizes the long line of cases in which conflicting testimony was not held to raise a genuine issue of fact sufficient to preclude summary judgment. *See* 622 F.2d at 893-94. Nowhere does the *Kennett-Murray* court disagree with the conclusions or analyses of these cases; it simply states that "the concerns raised in [such cases] are not present in this case." *Id.* at 895. This is not surprising since explanations for the inconsistent testimony were proffered in *Kennett-Murray* and the court spent considerable time analyzing these explanations. Thus, *Kennett-Murray* is easily distinguishable from cases, such as the present one, where no satisfactory explanation for a party's contradictory testimony is offered.

The case of *Dibidale of Louisiana, Inc. v. American Bank & Trust Co.*, 916 F.2d 300 (5th Cir. 1990), the only other case cited by Sinskey, is similarly distinguishable. Indeed, in *Dibidale* the court went so far as to find that the alleged

disparate testimony, when viewed in a light most favorable to the non-moving party, was not inherently inconsistent at all. *Id.* at 307. This finding clearly separates *Dibidale* from cases where no explanation for a party's inconsistent testimony is presented.

The circuit court decisions are completely uniform in holding that a party's subsequent declaration does not create a genuine issue of material fact when it contradicts, without satisfactory explanation, the party's prior testimony. No case cited in Sinskey's petition is contrary to this well-established rule. Thus, Sinskey has failed to demonstrate that his petition should be granted on grounds that a conflict exists in the circuit courts.

II. THE FEDERAL CIRCUIT'S DECISION PRESENTS NO IMPORTANT QUESTION OF LAW FOR THIS COURT TO CONSIDER

In his petition, Sinskey mischaracterizes the Federal Circuit's decision in an attempt to create the impression that an important question of law, requiring the attention of this Court, has been raised by the Federal Circuit's opinion. Specifically, Sinskey states that "the Appeals Court authorized a general rule that non-contemporaneous evidence of experimental use could never withstand a summary judgment motion." Petition at 9. Sinskey then argues that, in applying this "general rule," the Federal Circuit took it upon itself to ignore certain testimony, thereby violating fundamental principles applicable to summary judgment proceedings laid down by this Court. Petition at 9-10. However, and contrary to Sinskey's assertions, no such "general rule" was adopted by the

Federal Circuit. Thus, Sinskey's argument is without merit and he has failed to establish that an important question of law is presented for this Court's review.

Specifically, in analyzing the question of whether Sinskey had adequately raised a genuine issue of material fact concerning the alleged experimental purpose associated with his pre-critical date IOL implantations, the Federal Circuit reviewed the law relating to experimental use. First, the court pointed out that "[t]o establish that an otherwise public use or sale does not run afoul of section 102(b), it must be shown that the activity was 'substantially for purposes of experiment.'" (A 9, *quoting Baker Oil Tools, Inc. v. Geo Vann, Inc.*, 828 F.2d 1558, 1564, 4 U.S.P.Q.2d 1210, 1214 (Fed. Cir. 1987).) The Court then noted that some objective evidence must be presented in order to support a showing of experimental use. (A 9.) Finally, the court made the following statement with regard to the evidence Sinskey had presented in support of his claim of experimental use:

> Post-hoc affidavit testimony alone, years after the events described and purporting to show an inventor's subjective experimental intent, will never satisfy the burden of establishing experimental use *in a case like this* where there is no contemporaneous evidence of experimental purpose and the objective evidence is to the contrary. (A 10, emphasis added.)

This statement makes it clear that, notwithstanding Sinskey's assertions to the contrary, the Federal Circuit did not adopt a "general rule that non-contemporaneous evidence of experimental use could never withstand a summary judgment motion." Rather, the Federal Circuit

articulated a narrow rule tailored to the facts of this case. The Federal Circuit stated that where there is no contemporaneous evidence of experimental purpose and the objective evidence is to the contrary, mere affidavit testimony presented years after the events described could not satisfy the burden of establishing experimental use.

This narrowly tailored rule is a far cry from the "general rule" Sinskey claims was laid down by the Federal Circuit. More importantly, this rule is completely consistent with the Federal Circuit's prior decisions on this point, *see, e.g., Harrington Mfg. Co. v. Powell Mfg. Co.*, 815 F.2d 1478, 1481 n.3, 2 U.S.P.Q.2d 1364, 1366 n.3 (Fed. Cir. 1986), and presents no important question of law or departure from existing law requiring this Court's review.

III. THE FEDERAL CIRCUIT'S DECISION COMPORTS FULLY WITH ITS HOLDINGS IN PRIOR "EXPERIMENTAL USE" CASES AND IS FULLY SUPPORTED BY THE FACTS AND CIRCUMSTANCES SURROUNDING THIS CASE

The final argument in Sinskey's petition is that the Federal Circuit's decision constitutes a failure to follow the established case law in experimental use cases and should therefore be reviewed by this Court. This argument is completely without merit.

Although Sinskey correctly sets forth the law associated with experimental use, he completely fails to demonstrate that that law was incorrectly applied in this case.

More particularly, Sinskey sets forth the factors to be examined in determining whether a use was experimental. These factors include:

> [T]he necessity for public testing, the amount of control retained over the operation, the extent of public testing in relation to the nature of the invention, the length of the test period, whether any payment was made, whether there was a secrecy obligation, whether progress records were kept, who conducted the experiments, and the degree of commercial exploitation during the tests in relation to the purpose of the experimentation.

Baker Oil Tools, 828 F.2d at 1564, 4 U.S.P.Q.2d at 1214 (citations omitted). No single factor in the experimental use analysis is dispositive, and a determination on the issue should only be made after considering the entire surrounding circumstances. *T. P. Laboratories v. Professional Positioners, Inc.*, 724 F.2d 965, 971, 220 U.S.P.Q. 577, 582 (Fed. Cir. 1984).

Notwithstanding these considerations, Sinskey argues that, because there is a facial similarity between the facts in *T. P. Laboratories* and the present case, the Federal Circuit's decision in this case is inconsistent with its decision in *T. P. Laboratories* where the court found that certain conduct was experimental in nature and did not give rise to a public use bar to patentability. However, Sinskey's argument is fatally flawed in that, under the "totality of the circumstances" approach mandated by *T. P. Laboratories*, he has completely failed to come forward with objective evidence sufficient to overcome summary judgment.

Indeed, as the Federal Circuit noted, "[t]he objective evidence in this case cuts heavily against experimental

use." (A 10.) The Federal Circuit succinctly summarized this objective evidence as follows:

> Sinskey charged his usual surgical fee of $1,900 for each of the eight operations and IOLAB charged its standard $250 price for the lenses. He did not inform the patients that they were being treated with a "new" or "experimental" lens, nor did he obtain any kind of secrecy agreement from the patients or surgical staff. None of the documents provided by IOLAB or Sinskey ever referred to the Model 103J as "experimental" or the subject of tests. Apparently, routine medical records of these implantations were kept, but Sinskey does not refer to them specifically, and they were not put before the district court. If they contained any indication that the implantations were part of an experimental or test program, rather than routine operations, it is fair to assume Sinskey would have offered them. Besides, in its Premarket Approval Application to the FDA, IOLAB characterized the Sinskey lens as "equivalent in design, use and function to the Shearing . . . Lenses" and requested that it be "approved at this time as a supplement to the Shearing" lenses. (A 10-11.)

The Federal Circuit went on to point out that Sinskey presented no evidence, subjective or otherwise, contemporaneous with his initial implant operations that would corroborate his claims that these operations were for experimental purposes. (A 11.)

Based on the existing objective evidence and Sinskey's lack of evidence to the contrary, the Federal Circuit affirmed the trial court's determination that, within the

context of demonstrating an experimental use, Sinskey had failed to raise a genuine issue of material fact and thereby avoid summary judgment.

Nothing in Sinskey's petition demonstrates that the Federal Circuit failed to follow prior applicable case law or that the court's analysis in this case was somehow faulty. All that Sinskey argues is that "[t]he facts in *T. P. Laboratories*, [are] remarkably similar to the facts in this action," and, since this action was decided differently than *T. P. Laboratories* the Federal Circuit must be wrong. However, an examination of the facts in *T. P. Laboratories*, within the context of the factors to be considered in an experimental use analysis, shows that *T.P. Laboratories* is easily distinguishable from the present case.

First, although it is correct to say that both the inventor in *T. P. Laboratories* and Sinskey lacked secrecy agreements with their patients, there ends any similarity between the two cases. In *T. P. Laboratories*, the invention involved orthodontic devices which were labeled "experimental." 724 F.2d at 967, 220 U.S.P.Q. at 579. Sinskey has produced no evidence that the lenses he implanted prior to the critical date were designated "experimental." Further, IOLAB's November 16, 1979 Engineering Change Notice states that the Model 103J "has been added to our existing models." (Appeals Court Appendix at 436.) There is no indication on the document that the lens was in any way experimental.

Also, the nature of the invention in *T. P. Laboratories*, i.e., orthodontic devices requiring long periods of monitoring to determine if they were working properly, is dramatically different from the nature of Sinskey's

device. As Sinskey testified, the only test he needed to make was to determine how easy the lens was to implant. (Appeals Court Appendix at 404.) This determination was immediately made during the first implant procedure.

Finally, in *T. P. Laboratories*, the product's inventor was also its manufacturer, and even though the inventor/manufacturer could have sold the orthodontic devices during the experimentation period, it elected not to offer the devices for sale. *Id.* at 972-73, 220 U.S.P.Q. at 583. In contrast, Sinskey's licensee, IOLAB, sold at least three Model 103J lenses prior to the critical date.

Thus, *T. P. Laboratories* is easily factually distinguishable from the present case and Sinskey's reliance on *T. P. Laboratories*, to show that the Federal Circuit's decision in this case is not in accord with its previous holdings in experimental use cases, is misplaced.

CONCLUSION

For each of the foregoing reasons, a writ of certiorari should be denied.

Dated: April 27, 1993

Respectfully submitted,

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